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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCK	CONFIRMATION NO.
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24232	7590	12/18/2002		EXAMINER
DAVID R PRESTON & ASSOCIATES 12625 HIGH BLUFF DRIVE SUITE 205 SAN DIEGO, CA 92130				LU, FRANK WEI MIN
			ART UNIT	PAPER NUMBER
			1634	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/648,081	WANG ET AL.
Examiner	Art Unit	
Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 September 2002 .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 44-48,53-56,64-68 and 82-121 is/are pending in the application.
4a) Of the above claim(s) 44-48,53-56,64-68,84,86,99,100 and 110 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 82,83,85,87-98,101-109 and 111-121 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 22 July 2002 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____ .
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10, 13 . 6) Other: _____ .

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 82-100 and 108-12, species RNA (claims 83 and 109), species said known or suspected SNP or mutation is at a terminus of said probe (claim 85), and species one or more paramagnetic particles (claim 98) in Paper No. 15 is acknowledged. The traversal is on the ground(s) that:" [T]his election is made with traverse because of the commonality of the subject matter of the two Groups.".

The above argument has been fully considered and has not been found pervasive toward the withdrawal of the restriction requirement such that Groups I and II will be examined together. As shown in previous office action in Paper NO: 14, Groups I and II were distinct and independent inventions since these inventions are directed to methods comprised of different method steps and are required different searches. For example, the search required for Group II such as step (c) of claim 101 is not required for Group I since amplification step in Group II is used to amplify a population of nucleolytic activity-protected nucleic acid molecules before these fragments hybridize with attached nucleic acid molecules in step d) of claim 101 while amplification step in Group I (see step d) of claims 97 and 108) is used to identify one or more attached nucleic acid molecules after a population of nucleolytic activity-protected nucleic acid molecules hybridize with attached nucleic acid molecules.

Therefore, the requirement is still deemed proper and is made FINAL.

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2. This application contains claims 44-48, 53-53, 64-68, and 101-107 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in People's Republic of China on August 24, 2000. It is noted, however, that applicant has not filed a certified copy of this foreign application as required by 35 U.S.C. 119(b).

Response to Arguments

In page 15, first paragraph of applicant's remarks in Paper No. 11, applicant stated “[A]pplicants will supply a certificated copy of an application filed in Peoples' Republic of China on August 24, 2000 at a later date after allowable subject matter is established.”.

The examiner agrees that “[A]pplicants will supply a certificated copy of an application filed in Peoples' Republic of China on August 24, 2000 at a later date” . However, without a certified copy of this foreign application, this issue remains.

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

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The oath or declaration is defective because an alteration in page 3 of the oath or declaration was made without an initial. See 37 CFR 1.52(c).

Response to Arguments

In page 15, first paragraph of applicant's remarks in Paper No. 11, applicant stated “[A]pplicants will supply a new oath at a later date”.

The examiner agrees that “[A]pplicants will supply a new oath at a later date”. However, without a new oath, this issue remains.

Drawings

5. The drawings correction submitted on July 22, 2002 are still objected to for reasons as stated on FORM PTO-948 (Rev. 03/01 or earlier) in Paper No. 14. Note that applicant did not respond to this objection. Applicant is required to submit a proposed drawing correction in reply to this Office action.

Information Disclosure Statement

6. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Note that applicant did not address this issue.

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Claim Objections

7. Claim 82 is objected to because of the following informality: Note that “SNP” is abbreviation. It can only be used after this phrase appears once.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 82, 83, 85, 87-98, and 108-121 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 82, 97, and 108 is rejected as vague and indefinite over step(b) of the claims because it is unclear how “a population of nucleolytic activity-protected nucleic acid molecules” can be generated if said probe-survey population mixture of nucleic acid molecules is DNA or RNA while a nuclease used in the assay is a DNase or a RNase. Note that DNase or RNase can completely digest all DNA or RNA in the reaction. Please clarify.

Response to Arguments

In page 22 of applicant’s remarks in Paper No. 11, applicant argued that “it is clear that the specification that nucleic acid molecules can be protected by being resistant to particular nucleases, for example, by being in the single stranded state, or by having nuclease-resistant lineage.”.

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This arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Although the specification shows that nucleic acid molecules can be protected by being resistant to particular nucleases such as S1 nuclease, the claims do not limit that nucleic acid molecules only can be digested by particular nucleases that do not completely digest nucleic acid molecules. The claims are directed to treat nucleic acid molecules with a nucleolytic activity . Note that the definition (see page 12, lines 4-9) of “a nucleolytic activity “ does not limit to particular nucleases although the definition gives several nuclease examples since the word “for example” in the definition does not exclude other possible nucleases including a DNase or a RNase.

11. Claim 94 is rejected as vague and indefinite because it is unclear what it intended. Note that a known or suspected SNP or mutation in claim 82 is located on the probe nucleic acid molecule and there is no known or suspected SNP or mutation on the nucleic acid attached to a solid support. However, claim 94 is directed to a known or suspected SNP or mutation located on the nucleic acid attached to a solid support. There is insufficient antecedent basis for this limitation in the claim in view of the phrase “said known or suspected SNP or mutation” since a known or suspected SNP or mutation in claim 82 is different from said known or suspected SNP or mutation are different. Please clarify.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claims 82, 83, and 87-93 are rejected under 35 U.S.C. 102(e) as being anticipated by Kris *et al.*, (US Patent No., 6,238,869, filed on June 21, 1999).

Regarding claims 82, 83, and 87-92, as shown in Examples 14 and 15, total RNA from mouse liver (a survey population of nucleic acid molecules as recited in claim 82) was mixed with a protection fragment having a oligonucleotide having 70 bp long (considered as a probe comprising DNA as recited in claim 87) wherein its 60 bases were complementary to mouse GAPDH. In fact, the probe could have substituted nucleic acids (considered as a probe with a known mutations as recited in claim 82) (see column 4). A fragment complementary to mouse GAPDH mRNA was used as a protection fragment while its complementary strand was used as a negative control (antisense fragment). RNA samples with protection fragments were heated to 90 °C for 5 minutes, and hybridizations were done by bringing samples to 70 °C and allowing them to cool slowly to room temperature over night as recited in step (a) of claim 82 and claim 83. Then S1 nuclease was added to digest single stranded nucleic acid in RNA-protected fragment complex as recited in step (b) of claim 82 and claims 88-90. Finally, the samples heated to 90 °C for 15 minutes and then 37 °C for 15 minutes to denature and destroy RNA recited in claim 83, neutralized with HCl, and incubated on MAPS plates (contained multiple nucleic acid probes as an array as claim 92) overnight in the presence of biotinylated detection oligonucleotide as recited in steps (c) and (d) in claim 82 wherein the surface of the MAPS plates could be made by different materials such as glass or silicon as recited in claim 91. The amount of signal

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decreased in parallel with decreasing amounts of mouse RNA (samples included 500, 170, 50, 5, or 0.5 μ g of total mouse RNA). Two control samples were included to which no S1 nuclease was added (for examples, see columns 4, 5, 14, 24, 35, 36, 38, and 45-47, and Figures 8, 9, 24, and 25).

Regarding claim 93, in the hybridization assay with the MAPS plate, the protected fragment must be at least partially complementary to one of immobilized nucleic acid on the MAPS plate.

Therefore, Kris *et al.*, teach all limitations recited in claims 82, 83, and 87-93.

Response to Arguments

In page 22, last paragraph of applicant's remarks in Paper No. 11, applicant argued that “[A]s to claim 82, Kris *et al.* do not teach or suggest the use of a probe that comprises an SNP or a mutation in methods of identifying one or more nucleic acid molecules.”.

This arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because Kris *et al.*, do teach the use of a probe that comprises a mutation in methods of identifying one or more nucleic acid molecules (see column 4 and above rejection).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kris *et al.*, (June 21, 1999) as applied to claims 82, 83, and 87-93 above.

The teachings of Kris *et al.*, have been summarized previously, *supra*. Kris *et al.*, taught that the probe could have substituted nucleic acids (see last paragraph of column 4).

Kris *et al.*, do not disclose a nucleic acid probe with a known mutation at a terminus of said probe as recited in claim 85.

However, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed a method of identifying one or more nucleic acid molecules as recited in claim 82 wherein a nucleic acid with a known mutation at its one of termini was used as a probe nucleic acid molecule (the protected fragment) in view of the patent of Kris *et al.*. One having ordinary skill in the art would have been motivated to modify the method of Kris *et al.*, because optimization of the position of a

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mutation on a probe nucleic acid molecule during the process for designing the probe nucleic acid molecule would have been obvious to one having ordinary skill in the art at the time the invention was made. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to optimize the position of a mutation on a probe nucleic acid molecule during the process for designing the probe nucleic acid molecule. Note that where the general conditions of a claim are disclosed in the prior art, it is not inventive, in the absence of an unexpected result, to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

16. Claims 95-97, 108, 109, 111-117, and 119-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kris *et al.*, (June 21, 1999) as applied to claims 82, 83, and 87-93 above, further in view of Zhao (US Patent No.6,448, 010, priority date: October 6, 1999).

The teachings of Kris *et al.*, have been summarized previously, *supra*. Kris *et al.*, do not teach to identify one or more nucleic acid molecule/nucleolytic activity-protected nucleic acid molecule complexes by labeling said attached nucleic acid molecule/nucleolytic activity-protected nucleic acid molecule complexes with at least one detectable label using at least one polymerase. Instead, in the patent of Kris *et al.*, one or more nucleic acid molecule/nucleolytic activity-protected nucleic acid molecule complexes was be detected using a biotinylated detection oligonucleotide (see above 102 rejection).

Regarding claims 95-97 and 108, Zhao teaches a method for detecting a mutation in a target nucleic acid sequence that comprises: attaching oligonucleotide primers to a substrate;

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hybridizing to the oligonucleotide primers a sample nucleic acid sequence which possibly contains a mutation; extending each oligonucleotide primer by one base using a reaction mixture comprising labeled ddNTPs and a DNA polymerase; and detecting a mutation in the sample nucleic acid sequence by detecting the presence of a labeled ddNTP which does not correspond to the identity of the base expected to be added to the primer through the process of primer extension. In this method, a complex formed by the primers and the sample nucleic acid sequence was be labeled and identified as recited in step d) of claims 95-97 and 108 (see abstract, columns 1, 2, 5, and 6). The substrate, which was considered as a solid support here as recited in claims 95, 96, and 108, was selected from a variety of materials such as beads as recited in claim 97 (see column 3).

Regarding claims 109 and 111-117, since these claims were identical to claims 83 and 87-93, which were rejected in above 102 rejection, the examiner considered that Kris *et al.*, taught the limitations recited in claims 109 and 111-117.

Regarding claim 119, the labeled ddNTPs could be labeled with a fluorescent dye, a chemiluminescent reagent, a radioactive label, a redox tag, or an electrically conductive tag (see column 1, last paragraph).

Regarding claims 120 and 121, detectable label could be different (Cy5 or Cy3 label) (see column 6, last paragraph).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have identified one or more nucleic acid molecule/nucleolytic activity-protected nucleic acid molecule complexes by

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labeling said attached nucleic acid molecule/nucleolytic activity-protected nucleic acid molecule complexes with at least one detectable label using at least one polymerase in view of the patents of Kris *et al.*, and Zhao. One having ordinary skill in the art would have been motivated to modify the method of Kris *et al.*, because the simple replacement of one well known nucleic acid detection method (ie., using a detection probe to detect attached nucleic acid molecule/nucleolytic activity-protected nucleic acid molecule complexes) from another well known nucleic acid detection method (ie., using primer extension to detect the attached nucleic acid molecule/nucleolytic activity-protected nucleic acid molecule complexes) would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since both methods are well known detection methods and replacement of one detection method from another detection method would not change the experimental results.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

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17. Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kris *et al.*, (June 21, 1999) and Zhao (October 6, 1999) as applied to claims 82, 83, and 87-93, 95-97, 108, 109, 111-117, and 119-121 above, further in view of Shah *et al.*, (US Patent No.5, 629,156, filed on December 29, 1994).

The teachings of Kris *et al.*, and Zhao have been summarized previously, *supra*.

Kris *et al.*, and Zhao do not disclose to use paramagnetic beads as solid supports as recited in claim 98.

Shah *et al.*, do teach to use paramagnetic beads as solid supports in a hybridization assay (see columns 8 and Example 1 in columns 9-14).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have used paramagnetic beads as solid supports in the method as recited in claim 98 in view of the patents of Kris *et al.*, Zhao and Shah *et al...* One having ordinary skill in the art would have been motivated to modify the method as recited in claim 98 because the simple replacement of one kind of beads with another kind of beads with known properties as a solid support (ie., paramagnetic beads) in a method of identifying one or more nucleic acid molecules would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the replacement of one kind of beads with another kind of beads with known properties as a solid support in a nucleic acid detection method would not change the experimental results.

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Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

18. Claim 118 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kris *et al.*, (June 21, 1999) and Zhao (October 6, 1999) as applied to claims 82, 83, and 87-93, 95-97, 108, 109, 111-117, and 119-121 above, further in view of Nielson *et al.*, (US Patent No. 5,773,257, published on Jun 30, 1998).

The teachings of Kris *et al.*, and Zhao have been summarized previously, *supra*.

Kris *et al.*, and Zhao do not disclose polymerases as recited in claim 118.

Nielson *et al.*, teach that enzymes including E. coli, DNA polymerase I, Klenow fragment of E. coli DNA polymerase I, T4 DNA polymerase, T7 DNA polymerase, recombinant modified T7 DNA polymerase, other available DNA polymerases, and reverse transcriptase could be used in primer extension assays (see columns 12 and 13).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have used one of DNA polymerases as recited in claim 118 such as T4 DNA polymerase in the method as recited in

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claim 108 in view of the patents of Kris *et al.*, Zhao and Nielson *et al...* One having ordinary skill in the art would have been motivated to modify the method as recited in claim 108 because the simple replacement of one kind of DNA polymerase with another kind of DNA polymerase with known properties (ie.,T4 DNA polymerase) in a method of identifying one or more nucleic acid molecules would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the replacement of one kind of DNA polymerase with another kind of DNA polymerase with known properties in a nucleic acid detection method would not change the experimental results.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. No claim is allowed.

21. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
December 13, 2002



W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600